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ABSTRACT

Eight self-contained lessons present information about topics of current interest in the Food and Drug Administration. Multidisciplinary in nature, the lessons can be integrated into ongoing activities in elementary or secondary level reading, math, language arts, social studies, science, art, health, consumer education, and home economics. The lessons are short and independent of one another, easily modified to grade level, and can be used to demonstrate the relevance of daily activities to educational concepts.The lessons focus on the following topics: nutrition, food safety, drug safety (prescription and over-the-counter drugs), radiological health, cosmetics, and how to make inferences on labels, in newspapers, and ads; to demonstrate a public concern for safe use of medicines; and to be aware of sources of and protection from radiation exposure from electronic products in the home and at school. For each lesson, information is given on grade level, objective, skills, materials, teaching procedures, follow-up activity, and evaluation ideas. The background material included with each lesson is adequate to enable the teacher to use the material without further research. (Author/AV)

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MINI LESSONS FROM FDA

Food and Drug Administration (DHEW)
Washington, D. C.

1976

SP010 934

MINI LESSONS FROM FDA

CONTENTS

Nutrition

Food Safety

Drug Safety (Rx and OTC)

Radiological Health

Cosmetics

How to Make a Complaint

INTRODUCTION

Today's world is rapidly changing - we see it everyday in the food we eat, the medicines we take, and the cosmetics we use. We see these changes in newspapers, on television, and especially in the marketplace as a barrage of new products come tumbling forth. In terms of some of these products, 1906, the year the Food and Drug Administration was created, seems almost prehistoric.

As food processing moved from the home kitchen and the village shop to large factories and processing plants, gaps in consumer protection began to appear. In the same way, the compounding of drugs by the family doctor is now a part of the past. Regulations for new drugs were needed. In 1938, a more powerful Federal Food, Drug, and Cosmetic Act was passed. As new problems came along, amendments were enacted. Today, this law remains the cornerstone in protecting the consumer in situations beyond his individual control.

Frozen dinners, instant coffee, and enriched foods now taken for granted were unheard of. There were no miracle drugs, no plastics, and perhaps, unbelievable to elementary school children, no television.

This progress in food technology and development of new drugs increases the responsibilities of Federal agencies which operate solely for the protection of the public. Virtually every product in a supermarket or drugstore is in some way regulated by FDA. New legislation for expanding consumer protection has been passed by Congress and a constant vigilance must be kept by FDA.

The FDA people are scientists - physicians, chemists, nutritionists, microbiologists, and pharmacologists; they are consumer safety officers who inspect manufacturing plants and investigate consumer complaints; they are lawyers and compliance officers who interpret and enforce the laws; they are consumer affairs officers trained to work with consumers, educators, and communicators.

The marketplace for this country is no longer made up of individual things that individual consumers buy and take home. America wants an enriched quality of life. Government and schools provide regulations and education as a team to protect our society.

Students need basic information in order to participate in the evolution and enforcement of laws and regulations in a meaningful way. Government can provide this background. It is an exciting challenge for FDA to be a part of an education endeavor for students, parents, teachers, and community leaders.

The mini lessons included here have been prepared by FDA Region V. We hope communication through these mini lessons is the beginning of a dialogue between FDA and schools. Consumers who are truly aware of their role are a basic part of our consumer protection effort.

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DESCRIPTION OF MINI LESSONS

PURPOSE

The primary objective of "A Mini Lesson from FDA," is to make available to teachers the most recent information about FDA topics of current interest in such a way that materials will be directly useful in ongoing curricula.

THE MINI LESSON PLAN

"A Mini Lesson from FDA" involves imaginative teaching techniques.

The lessons are:

- Short in duration
- Independent of one another
- Self-contained

The lessons can be:

- Integrated into ongoing curricula
- Easily modified to grade level
- Combined to develop an intensive FDA unit

The lessons can be used:

- In multidisciplinary approaches
- To develop various specific skills
- To demonstrate relevancies of normal daily activities

INTERDISCIPLINARY

When teachers review the lessons for use in their classroom, they will be facing a choice of selecting information about FDA or about other worthwhile topics. In order to provide greater usefulness to the teachers, the lesson procedures have multiple purposes which extend beyond teaching about FDA. The mini lessons provide greater utility for the creative and innovative teacher by having suggestions for developing skills, follow up, and evaluation. For the majority of the teachers, the information included with the lesson will be adequate to use without research. Existing courses in which "A Mini Lesson From FDA" can be integrated are: language arts, social studies, science, consumer education, reading, math, health, and art.

THE STUDENTS' NEED FOR CURRENT FDA INFORMATION

For regulatory agencies to be really effective, knowledge of current and proposed "laws" must become a part of the thinking of the total citizenry. There is need for greater citizen recognition of their interdependence, one with another. Education about FDA is a continuous process. FDA information is multidisciplinary in nature. It is for multi-age levels; all citizens, birth to death, need to know their "rights, and how FDA improves the quality of their lives. However, most adults today depend upon FDA education from promotional mass media messages and from their own experiences in the marketplace. Few know their "responsibilities" in the Federal regulatory process.

PERFORMANCE GOALS

For the most part, the lessons develop broad understanding and attitudes; they are concerned with activities with which the students are likely to be familiar. A few examples are:

The student will:

- Recognize important nutritional terms and locate these on nutrition information panels of food packages.
- Observe on food labels, differences in nutritional value, and recognize the benefits of planning for good nutrition.
- Look more carefully at subtle inferences on labels, in newspapers, and ads.
- Distinguish between nutrition labeling, ingredient labeling, and standardized food labeling.
- Be aware of terms and the type of information contained on labels of over-the-counter (OTC) medicines and in commercial advertiaing.
- Recognize the multitude of OTC drugs in common use, and will respect them as potentially harmful drugs.
- Demonstrate a public concern for safe use of medicines, and will realize important precautions.
- Be able to identify the risk benefit principle as it applies to diagnostic x ray as a medical aid.
- Be aware of sources of and protection from radiation exposure from electronic products in the home and at school.
- Identify cosmetic-like products which are regulated as a drug.
- Realize the opportunity and responsibility to report harmful products to appropriate regulatory agencies.

MINI LESSON TOPICS

The FDA priority education programs include the subject areas for:

- "New" nutrition label on canned and packaged foods
- Practical information on food storage and sanitation
- Guidelines for prescription and over-the-counter drug safety
- How to make a complaint to FDA
- The latest information on use of electronic products
- New regulations on cosmetic products

The seven topics included in this kit are:

- NUTRITION: Using the U.S. RDA (U.S. Recommended Daily Allowance)
- FOOD SAFETY: Food Handling Habits in the Home.
- DRUG SAFETY: Pay Attention to Over-the-Counter (OTC) Drug Label Information.
- DRUG SAFETY: Handbill on Drug Safety
- RADIOLOGICAL HEALTH: Non-Diagnostic Radiation Safety
- COSMETICS: New Regulations on Cosmetic Products
- A REPORT TO FDA: Business Letter to FDA

RELEVANT APPROACHES

In the proecedure suggested for each mini lesson, an attempt is made:

1. To begin with ideas which students already have.

2. To provide an interesting experience on which to build the lesson.

REFERENCES

Teachers may wish to obtain copies of publications listed in mini lesson references for students to take to their families. Check with your FDA office for the publications available in quantity. Check with your own school library for the periodical, FDA Consumer.

FOLLOW UP

Lessons include follow up. Based on the interest of the students and/or needs identified by the teacher, the depth, scope and length of the "mini lesson" can be modified to include more information or more topics.

EVALUATION IN THE CLASSROOM

Evaluation suggestions have been included. Teachers can develop or use other techniques for judging:

1. The extent of changes in skills.

2. The knowledge students gained.

3. Changes in attitudes toward regulatory agency functions and services.

A WORD OF CAUTION

It is possible for the teacher to adjust the mini lesson in various ways. However, unnecessary duplication from grade to grade must be avoided. The plan must neither be rigid nor directionless. In the overall plan of the curriculum supervisor or the program director, the mini lessons offer both variety and perspective.

A MINI LESSON FROM FDA

NUTRITION

Topic: Using the U.S. RDA (U.S. Recommended Daily Allowance)

Level: Middle and Upper Grades

Objective: The student will give consideration to information contained on nutrition labels, know how to observe differences in nutritional value of various foods, and how this can be used in planning for good nutrition.

Skills: Adding percentages, using metric system, and group planning.

Materials: Nutrition Yardstick which includes chart of U.S. RDA and nutrition information on peas (groups and individuals).

Procedure:

1. Divide the class into small groups (4-5). Give each group a copy of the nutrition yardstick.

2. Assign each group to collectively gather nutrition labels from food products in the home to be brought into class.

3. Repeat the procedure over several days until each child in the group has kept a daily record on the Nutrition Yardstick.

   (a) Each day, identify the group which comes closest to meeting the total U.S. RDA standards. Make a chart listing nutrients on the chalkboard for the group identified.

   (b) Each member of the group should bring something to meet the requirements thereby causing them to discover the need for planning.

   (c) Each day, members of the winning group might get some form of special recognition.

4. Packaged foods to which nutrients have been added or that make nutritional claims are required to provide nutrition information labeling. It should be clearly understood that all food labels do not provide "nutrition information." Many foods such as vegetables, fruits, cereals, fish, dairy products, sugar, breads, potatoes, and oils are rich sources of nutrients.

Follow Up: Make a collage of the labels that were brought in. Conduct interviews about nutrition. Find out what kinds of nutrients are in unpackaged foods.

Code for test answers on page 2

A. True=1,4,6,7 False=2,3,5

B. True=1,2,6 False=4,5

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Evaluation: Use the information on the bottom of the Nutrition Yardstick form for testing or discussion.

A. Cluster True-False. Mark a T for those statements that are true about nutrition labeling and an F for those statements that are false.

_____ 1. Nutrition labeling makes nutrition information available to everyone who wants to use it.

_____ 2. Nutrition labeling is required of all foods.

_____ 3. The nutrition label lists the types of fats that are good for you.

_____ 4. The nutrition label shows percentages of the U.S. RDA.

_____ 5. Nutrition labeling forces everyone to eat things that are good for them.

_____ 6. The nutrition information panel tells how many servings or portions are in the container.

_____ 7. Calories per serving must be shown on the nutrition information label.

B. Circle true, false, or does not say (NS).

1.	The peas contain 8% of the U.S. RDA of niacin.	T	F	NS
2.	The nutrition information listed is per serving.	T	F	NS
3.	The peas are fortified with nutrients.	T	F	NS
4.	The U.S. RDA is listed in cupfuls.	T	F	NS
5.	Vitamin A is higher in peas than Vitamin C.	T	F	NS
6.	The peas contain 1 gram of fat.	T	F	NS

Reference:

"Food is More Than Just Something to Eat," USDA and HEW in cooperation with the Grocery Manufacturers of America and the Advertising Council, courtesy of U.S. DHEW/PHS/Food and Drug Administration, Rockville, Md.

"Read the Label, Set a Better Table" - A Guide to Nutrition Labeling from The Food and Drug Administration.

NUTRITION YARDSTICK

Nutrition Labels and U.S. Recommended Daily Allowances

Breakfast | Lunch | Dinner | Snacks

Name: _____

Class: _____

Date: _____

	1	2	3	4	5	6	7	8	Total
FOOD AND SIZE OF SERVING ON LABEL									
Name of Food									
Serving Size on Label									
NUTRITION INFORMATION FOR THE SERVING SIZE YOU SELECTED									
Serving Size									
Calories									
Protein									
Carbohydrate									
Fat									
PERCENTAGES OF U.S. RECOMMENDED DAILY ALLOWANCES FOR YOUR SERVING SIZE									
Protein									
Vitamin A									
Vitamin C									
Thiamin (B_1)									
Riboflavin (B_2)									
Niacin									
Calcium									
Iron									

The following chart lists the U.S. Recommended Daily Allowances for use in nutrition labeling (g–gram, IU–International Unit, mg–milligram, and mcg–microgram).

	Adults and Children		Adults and Children
Protein	**65 g***	**Vitamin B_6**	**2.0 mg**
Vitamin A	**5,000 IU**	**Folacin**	**0.4 mg**
Vitamin C	**60 mg**	**Vitamin B_{12}**	**6 mcg**
Thiamine	**1.5 mg**	**Phosphorus**	**1.0 g**
Riboflavin	**1.7 mg**	**Iodine**	**150 mcg**
Niacin	**20 mg**	**Magnesium**	**400 mg**
Calcium	**1.0 g**	**Zinc**	**15 mg**
Iron	**18 mg**	**Copper**	**2 mg**
Vitamin D	**400 IU**	**Biotin**	**0.3 mg**
Vitamin E	**30 IU**	**Pantothenic Acid**	**10 mg**

*** If protein efficiency ratio of protein is equal to or better than that of casein, U.S. RDA is 45 g.**

PEAS

NUTRITION INFORMATION, per serving

Serving Size = 1 cup Servings per container = 2

CALORIES	110	CARBOHYDRATE	20 grams
PROTEIN	7 grams	FAT	1 gram

PERCENTAGE OF U. S. RECOMMENDED DAILY ALLOWANCES (U.S. RDA)

PROTEIN	10	NIACIN	8
VITAMIN A	20	CALCIUM	4
VITAMIN C	35	IRON	10
THIAMINE	10	PHOSPHORUS	10
RIBOFLAVIN	8	MAGNESIUM	6

FDA

Consumer MEMO

CURRENT AND USEFUL INFORMATION FROM THE FOOD AND DRUG ADMINISTRATION

METRIC MEASURES ON NUTRITION LABELS

One of the first things consumers will notice about the new nutrition information food labels is that metric units are used throughout. These are the measuring units used in most of the world.

The metric system is based on the decimal system of numbers, which involves multiples of 10. Thus, it is very easy to go from small units to large, or vice versa, by simply moving decimal points.

The Food and Drug Administration prescribed the metric system for nutrition labels because the unit we are most accustomed to, the ounce, is too large to describe conveniently the amounts of nutrients in foods. For instance, 1 gram is about equal to the weight of a paper clip. If a food contains 9 grams of protein, then, expressing this in our customary terms, it would be 9/28 ounce. This is just an example of how customary measurements used for food composition would not only be very small but appear as confusing fractions.

The basic metric units that consumers will see on nutrition labels are grams (units of mass or weight) and liters (units of volume). Metric units of volume may appear in the serving size for liquid foods as well as in the container's net volume. The upper portion of the label will use metric units in weight as grams for protein, carbohydrate, and fat in a serving of food.

The lower portion of the nutrition information panel gives the *percentage* of the U.S. Recommended Daily Allowances of protein, vitamins, and minerals in a serving, and does not require any understanding of the metric system.

It may help to memorize these approximate equivalencies:

One ounce = 28 grams

Three and one-half ounces = 100 grams

Eight ounces = 227 grams

One pound = 454 grams

Once the basic unit is determined, whether grams or liters in the metric system, other multiples are built on it with suitable prefixes. Whenever the prefix "kilo" precedes a unit, it is 1,000 times that unit. One kilogram equal 1,000 grams, for example.

Similarly, the prefix "milli" indicates one-thousandth and "micro" one-millionth of the basic unit. A milligram is one-thousandth of a gram.

Thus:

1 kilogram = 1,000 grams

1 gram = 1,000 milligrams

1 milligram = 1,000 micrograms

To convert the metric system into the system to which Americans are more accustomed:

1 kilogram = 2.2 pounds

1 pound = 454 grams

1 ounce = 28 grams

The other basic unit of metric measurement besides the gram that will be found on nutrition labels is the liter, used to measure volume.

A liter is a little larger than a quart.

1 kiloliter = 1,000 liters

1 liter = 1,000 milliliters

To translate this system into the one currently used in the United States:

1 gallon = 3.79 liters

1 quart = .95 liters
or 950 milliliters

1 pint = .48 liters
or 480 milliliters

1 cup (8 fluid ounces) = .24 liters
or 240 milliliters

1 tablespoon = 15 milliliters

1 teaspoon = 5 milliliters

Remember the saying "A pint is a pound, the world around"? Well, this is a rough approximation based on a volume-weight relationship of water. A pint of food that contains more fat than water will weigh less than a pound.

These same relationships of volume to weight and fat to water carry through to the metric system. Here is a new twist to an old saying to help you remember that pints and liters are volume measurements and pounds and kilograms are weight:

A pint is a pound the world around, but
A liter is a kilogram
When you're in a metric jam.

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE Public Health Service Food and Drug Administration
5600 Fishers Lane Rockville, Md. 20852 March 1974 DHEW Publication No. (FDA) 74-2022

FOR ADDITIONAL INFORMATION WRITE OR TELEPHONE THE FDA OFFICE WHICH SERVES YOUR STATE.

ADDRESS TO: CONSUMER AFFAIRS
FOOD AND DRUG ADMINISTRATION

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__ Labels on Foods
__ Nutrition Labels on Food
__ Read the Label, Set a Better Table

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Highlights (3 1/2 X 8 inch card)
__ It Pays to Use Cosmetics with Care
__ Guard Against Food Contamination in the Kitchen
__ Plan a Better Diet - Save Money Too
__ Non-prescription Medicines
__ Safe Use of Medical X-Rays
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NAME _____ TITLE _____
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STREET _____ CITY _____ STATE _____ ZIP _____
MAJOR AREA OF INTEREST _____ EDUCATION GRADE LEVEL _____

A MINI LESSON FROM FDA

FOOD SAFETY

Topic: Food Handling Habits in the Home.

Level: Middle and Upper Grades

Objective: To recognize some basic health practices used in storage, preparation, and consumption of food.

Skills: Listening for details

Materials: (1) Story about Senseless Sal; (2) Health Habits check list; (3)Handout "Guard Against Food Contamination," DHEW Publication No. (FDA) 74-2047. (one for each child).

Procedure:

1. Give students the handout, "Guard Against Food Contamination."

2. Have the students work the Health Habits Check List.

3. Give each child a red flag made from construction paper. As you read the story, the students are to wave the flag each time they hear Senseless Sal doing something which is unwise. Stop periodically and discuss what has happened.

Follow Up: Write a story about other safety habits.

Evaluation: This activity can be a learning or evaluation exercise.

HEALTH HABITS CHECK LIST

Do I??? (A) always, (S) sometimes, (N) never.

1.	Do I wash my hands with soap and water before eating?	A	S	N
2.	Do I close the refrigerator door?	A	S	N
3.	Do I put the milk away at once after pouring some for myself?	A	S	N
4.	Do I help mother put leftovers in covered bowls for storing?	A	S	N
5.	Do I put the leftovers in the refrigerator promptly?	A	S	N
6.	Do I check canned foods for leaks or bulges?	A	S	N
7.	Do I wash dishes with hot water and soap?	A	S	N
8.	Do I rinse the dishes with very hot water?	A	S	N
9.	Do I help mother put the groceries away quickly?	A	S	N
10.	Do I put the mayonnaise in the refrigerator after I finish using it?	A	S	N

Reference:

"Guard Against Food Contamination," DHEW Publication No. (FDA) 74-2047.

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GUARD AGAINST FOOD CONTAMINATION

When you get an upset stomach or diarrhea, it may not be "just a bug."

You could have foodborne illness. Many such illnesses are caused by harmful bacteria in food.

You can prevent foodborne illness by remembering these words:

In your kitchen, keep hot foods hot. Keep cold foods cold.

Proper cooking and proper refrigeration can control bacterial growth in the foods in your kitchen.

Protect yourself and your family. Follow the safety rules below.

IN THE KITCHEN

1. Clean your hands and work surfaces before and after handling raw foods, particularly meat and poultry.

2. In handling raw foods, wash all utensils in hot soapy water.

3. When cooking meats and poultry, use a thermometer. Cook the inside of the food to the proper temperature. Look this up in a cook book.

4. Put perishable foods in the refrigerator as soon as you get home from the store. The same with frozen foods. Put them in the freezer right away.

5. Put leftovers in the refrigerator as soon as you finish eating.

6. Defrost frozen foods in the refrigerator, not on the counter top.

7. If a food doesn't look or smell right, don't eat it.

SENSELESS SAL

This is a story about Senseless Sal and her daughter, Dill. Sal and Dill do many things which are unhealthy. Listen to see if you can spot them.

[*Senseless Sal is in the kitchen, daughter Dill is in the backyard*]

Sal : Dill, Dill, stop playing with that dog and come in for lunch.

Dill: What are we having? Oh! Tuna salad, we had that last night for supper. I put the leftovers away before I went to bed.

Sal : Wash your hands before you eat.

Dill: Do I have to?

Sal : I suppose not, a few germs never killed anyone!

Dill: What will we have for supper tonight?

Sal : I think we'll have fried chicken. If I take it out of the freezer now and put it on the counter, it will be thawed out by the time I want to fix it. I need to go to the store this afternoon.

Dill: Can I go with you? You said we could shop for a new dress.

Sal : We'll go to the grocery store first and then to the department store.

Dill: Should I put this mayonnaise away?

Sal : Just put it on the counter and let's get going. I'll put it in the refrigerator after while.

[*Senseless Sal and Dill enter the supermarket*]

Sal : Now, let me see, I need milk, fresh pork, and frozen vegetables. I'll get those first and then go through the store and get anything else I need.

[*As they push the carts through the aisles ...*]

Dill: Look at this funny can of mushrooms, the two ends look like they are pushed out.

Sal : Just put it back on the shelf and let's go check out. It's a warm day and the department store is air-conditioned. We can take our time there.

[*After two hours of shopping, Sal and Dill return home.*]

Sal : I'll get that chicken started before I put these groceries away.

Dill: After you start the chicken, can we make some cookies?

Sal : Sure, you get out the ingredients. Did you wash off the counter?

Dill: No.

Sal : Oh, never mind, it looks clean.

Dill: Is this cracked egg okay to use?

Sal : We'll use it. Can you finish the lunch dishes while I start the cookies?

Dill: The water is cold.

Sal : That's okay, if it's got plenty of soap in it. Just wipe out that bowl that the chicken was in. I need it to mix the cookie dough.

Dill: I want to eat the dough that is left in the bowl.

Sal : Okay! There, now the cookies are baking and I can get those groceries put away. I don't have a covered dish to put this pork in so I'll just put it on a plate in the fridge.

Dill: What else will we have for supper?

Sal : I guess we'll have a quart of those home canned green beans Grandma put up last summer. We better eat this one first, the lid seems to be leaking.

Dill: The cookies are done.

Sal : Good, soon your Father, Hopeless Hal, will be home. He went to the doctor. He's suffering from stomach-aches and he had diarrhea again.

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A MINI LESSON FROM FDA

DRUG SAFETY

Topic: Drug Safety - Seek-a-Word.

Level: Intermediate

Objective: The student will recognize and use terms related to over-the-counter (OTC) drug terms.

Skills: Identifying positions by coordinates

Materials: Drug Safety - Seek-a-Word

Procedures:

1. Students can do this exercise independently or in a group.

2. As a group activity, teach math concepts of coordinates.

   (a) Locate drug terms on Drug Seek-a-Word.

   (b) Identify the location of the term using the numerical coordinates. For example, the "D" in the word drug coordinates 16 up and , to the right; 'G" is 13 up and 9 to the right.

   (c) The direction in which the words are written may be forward, backward, up, down, or diagonally.

Follow Up: Students select ten additional words from the following simple rules on drug safety, and prepare a new Seek-a-Word.

DON'T

--Be casual about taking over-the-counter drugs.
--Keep drugs for long periods of time.
--Combine drugs carelessly.
--Continue taking OTC drugs if symptoms persist.
--Take prescription drugs not prescribed specifically for you.

DO:

--Read the label and follow directions for use.
--Be cautious when using a drug for the first time.
--Dispose of old prescription drugs and outdated OTC medications.
--Seek professional advice before combining drugs.
--Seek professional advice when symptoms persist or return.

Evaluation: Student demonstrates:

1. Greater recognition and increase use of drug terms.

2. Ease in the use of coordinates.

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DRUG SAFETY - SEEK-A-WORD

The hidden terms listed appear forward, backward, up, down, or diagonally. Find each term and identify the coordinates for the first and last letter.

25	O	U	T	D	A	T	E	D	B	M	E	A	J	N
24	A	P	E	R	S	I	S	T	K	E	L	O	Q	S
23	S	Y	M	P	T	O	M	S	C	D	F	O	L	D
22	E	P	P	H	A	R	M	A	C	I	S	T	R	T
21	C	X	H	I	A	X	C	F	X	C	G	C	H	E
20	I	V	Y	D	L	A	B	E	L	I	L	N	M	E
19	V	J	S	M	O	L	K	P	R	N	S	I	V	O
18	D	W	I	X	Y	A	D	H	K	E	T	F	I	Z
17	A	G	C	A	P	S	U	L	E	S	M	P	L	C
16	O	R	I	S	N	D	A	N	G	E	R	O	U	S
15	F	D	A	P	T	A	R	Q	V	T	C	T	W	L
14	U	Y	N	L	Z	D	E	U	J	G	O	E	B	E
13	C	A	F	K	C	U	R	E	G	X	L	N	I	E
12	O	P	N	L	M	O	T	C	I	O	Q	C	N	P
11	M	C	W	T	Y	A	H	C	Z	C	F	Y	R	I
10	B	A	N	T	I	B	I	O	T	I	C	S	U	N
9	I	B	E	I	D	H	L	H	L	X	B	G	T	G
8	N	I	M	A	S	P	I	R	I	N	N	O	P	P
7	E	N	T	X	A	Z	R	S	A	F	E	T	Y	I
6	R	E	A	C	T	I	O	N	T	B	H	E	X	L
5	U	T	V	W	E	E	Y	D	K	A	F	M	C	L
4	I	P	J	S	G	R	N	P	C	K	M	G	U	S
3	A	Y	U	E	O	U	I	D	O	G	W	I	B	E
2	Z	A	F	C	L	C	H	I	L	D	R	E	N	B
1	C	A	R	E	L	E	S	S	V	A	X	C	T	E
	1	2	3	4	5	6	7	8	9	10	11	12	13	14

TERM

advice
alcohol
antibiotics
antihistamine
aspirin

cabinet
capsule
careless
cause
children
combine
cure

dangerous
drug

FDA

label

medicine

old
OTC (over-the-counter)
outdated

persist
pharmacist
physician
pill
potency

Rx (prescription)

safety
sleeping pills
symptoms

time

A MINI LESSON FROM FDA

DRUG SAFETY

Topic: Pay Attention to Over-the-Counter (OTC) Drug Label Information.

Level: Middle and Upper Grades

Objective: The student will be aware of the type of information contained on labels of OTC medicine including all necessary precautions.

Materials: Drug label work sheet, "Labels on Medicines" for teacher and parents, and one or two empty and clean OTC drug packages with insert and container for classroom demonstration.

Skills: Observation, reference (dictionary).

Procedure:

1. Write a few terms from drug labels like "orthophosphoric acid," "hydrogen ion concentration," etc. on the chalkboard. Play with the terms having the students read and pronounce them.

2. Discuss and demonstrate where the terms came from.

3. Give students the work sheet to record the information from on OTC drug label. They can look at labels in a drugstore or at home with parental knowledge and consent. Here is a sample letter requesting parent approval. If possible, include "Labels on Medicines," with the letter to parents.

   Dear Parent:

   This work sheet is part of your child's class work on medicine safety. Please note the information asked for and indicate your approval of the recording of this information from one package of non-prescription medicine in your home. Examples of such medicine would be aspirin, cold tablets, cough medicine, and others which can be purchased without a prescription from the doctor. Do not use information from prescription (Rx) drugs.

   _____ (signature) _____ (date)

4. When the students return the work sheet, discuss the various types of things that a consumer should notice on drug labels.

5. Have the students look up the definition of at least one of the long ingredient terms just for fun and for dictionary practice. Discuss prefixes and suffixes of medical terms.

Code for Cause and Effect True-False statements on page 2
True = 1, 2, 4, 8, 9, 10 False = 3, 5, 6, 7

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Follow Up: Bring someone to the class who can talk about the effect of OTC medicine on the body (a physician, nurse, etc.).

Evaluation: The following can be used later for discussion or testing:

A. Cause and Effect True and False. [This type of test must be explained carefully. Both parts can be true or false; one part can be true and the other part false]

_____ 1. Keeping medicine out of the reach of children is
_____ 2. important because they could accidentally poison themselves.

_____ 3. Information on the label of OTC drugs is not
_____ 4. important because they do not require a doctor's prescription.

_____ 5. Once you have read a label and know what it says,
_____ 6. you need not read it again because the labels never change.

_____ 7. OTC drugs can be safely used by everyone
_____ 8. because they are sold without prescription.

_____ 9. If symptoms persist, see your doctor
_____ 10. because you could have something very serious.

B. Spelling Exercise or Correct Word Usage

accidental	effective	consulting
cautions	frequently	directed
drowsy	ingredient	disease
headache	persist	dosage
overdose	prevents	medical
side effects	reaction	treatment
symptoms	relief	poisoning
warnings	temporary	prolonged

labels on medicines

Every year American consumers spend millions of dollars on medicines—some bought without prescriptions or "over the counter" (OTC drugs), and some prescribed by physicians.

All medicines have a potential for harm as well as good. So it is extremely important to read the labels on them carefully and thoroughly.

Labels on Over-The-Counter Medicines

Information on OTC drug labels includes:
Name or statement of identity of the product.
Net quantity of contents.
Active ingredients.
Name and place of business of the manufacturer, distributor, or packer.

Directions for safe use by the consumer.
This includes an indication of the symptom to be treated, plus dosage information, such as:
(1) Individual dose or unit dose
(2) How frequently it can be taken
(3) Total dose that should be taken in a day
(4) Limit on the length of treatment (or number of days it can be taken)
These directions should always be read with special care.

Warnings: Many OTC medicines should not be used by people with certain health problems, and the labels contain a warning. An example of such a warning is: "CAUTION: Should not be taken by persons with high blood pressure, heart disease, diabetes, or thyroid disease unless directed by a doctor."

Always read warnings carefully. A drug that is safe for others could be dangerous for you.

Side Effects: Labels on OTC medicines tell you about side effects, or unwanted reactions which may occur. For example, some medicines may make you drowsy, and the label will tell you not to drive or operate machinery when taking the drug.

"If symptoms persist . . ." OTC medicines are designed to help relieve symptoms. If your pain or other symptoms don't go away, don't continue to take OTC medicine. You may have an illness that should be treated professionally. Make an appointment to see your physician.

Labels on Prescription Medicines

Prescription drugs also have a label—written especially for you by your pharmacist as directed by your doctor. Instructions on the label tell you how much to take, and how often If you feel you need to take more—or less—call and ask your physician.

Unlike the labels on OTC drugs, the label on a prescription medicine does not usually tell you what it will do for you, side effects that may occur, special precautions you should take, and perhaps not even the name of the medicine. This information must come from the physician, and it is important that you understand his instructions and follow them as directed.

Every time you take medicine, read the label to be sure you are taking it correctly. Never take a medicine that was prescribed for someone else, and never let someone else take one that was prescribed for you.

Remember, prescription drugs are powerful and can be dangerous if not used properly.

Drug Labels and You

Labels are on medicines for a purpose. They tell you how to use medicines correctly. Labels on over-the-counter medicines are especially important because the label is your primary source of information for correct use.

The law requires that important information be given on labels, but the information is useless unless you read and use it. Make it a habit to read labels thoroughly and to follow directions exactly.

"Keep Out of the Reach of Children"
Many OTC drug labels include the admonition: "Keep out of the reach of children." Accidents with medicines, both OTC and prescription, account for a large number of child poisonings each year. This is why it is especially important to keep all medicines out of children's reach, in a locked cabinet or on a high shelf.

Under a law passed by Congress in 1970, FDA is now requiring that certain medicines be sold in containers with safety closures which are difficult for children to open. Adults should follow the directions on safety closures to learn how to use them. If you need help, ask your pharmacist.

WORK SHEET

WHAT DOES THE DRUG LABEL SAY?

If your eyes are good and you can read small print, you should be able to find all this information printed on every label of every over-the-counter drug package.

1. What is the name of the product? _____

2. What is the name and address of the manufacturer, distributor, or packer?

_____

3. How much does a full package contain? _____

4. What is the product used for? _____

_____

5. What are the directions for safe use of the drug?

6. Does it have special WARNINGS or CAUTIONS ?

7. Are there any SIDE EFFECTS ?

8. What active ingredients are in the product?

9. You probably found some very long words. Write down some words you do not know. Find these words in the unabridged dictionary; write down the meaning.

Words: (1) _____

(2) _____

(3) _____

A MINI LESSON FROM FDA

DRUG SAFETY

Topic: Handbill on Drug Safety.

Level: Middle and Upper Grades

Objective: The student will demonstrate a public concern for safe use of prescription (Rx) and over-the-counter (OTC) drugs.

Skills: Critical thinking, summarization, art, and design.

Materials: Information on drug safety from FDA.
State Public Health.
Poison Control Center.

Procedures:

1. The class will jointly prepare a list of safety precautions to be followed with drugs used in the home. Gather information on using OTC and Rx drugs.

2. Plan an interesting handbill which presents the most important precautions.

3. After a satisfactory design has been developed, use a ditto machine and print the handbills.

4. Distribute these at the neighborhood shops, schools, and public libraries. Ask store owners to put the handbill on the check-out counter. The class should provide a "Take one" sign. Don't forget to identify the school and class.

Follow Up: Do a neighborhood survey to find out who saw the handbill and what they learned from it.

Evaluation:

1. Tabulate the number of locations, number of handbills distributed, and number of individuals who reported receiving handbill.

2. Analyze the responses collected through the neighborhood survey.

3. Question the students themselves on the information contained in the handbill.

References:

Attached

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ASPIRIN

Aspirin (acetylsalicylic acid) belongs to the group of drugs, known as salicylates. It is a popular self-medication for the relief of headache, minor pains, and reduction of fever.

Bufferin - a comparison with plain aspirin.

The essential ingredient of Bufferin is aspirin. Most of the published studies indicate there is little difference in the incidence of stomach upsets after ingestion of Bufferin or plain aspirin. There is no evidence to indicate that the speed of onset of its action in relieving pain is significantly increased over plain aspirin.

Side Effects

Although aspirin does not frequently cause side effects. The following have been reported:

1. Gastro-intestinal irritation: Symptoms are indigestion, nausea, and bleeding.
2. Allergic reactions are: Skin rashes, asthmatic attacks, loss of consciousness.
3. Salicylism--a condition produced by ingestion of large doses of aspirin or other salicylates. Symptoms are ringing in the ears, headache, dizziness, and mental confusion.
4. Frequent doses of aspirin if too-long-continued can cause kidney damage.
5. Infant and children deaths have occurred from acute poisoning.

Warnings

1. Do not give aspirin indiscriminately, especially to infants and children.
2. Keep all aspirin medications out of the reach of children.
3. Patients with a history of allergy to salicylates should avoid taking aspirin.
4. Individuals who are allergic or who have a history of stomach ulcer should avoid aspirin as much as possible.
5. Bleeding, including vomiting of blood, following ingestion of aspirin requires immediate medical attention.
6. Ingestion of large doses of aspirin by children requires immediate medical attention.

Accidental Poisoning in Children

Aspirin continues to be the medicine most frequently involved in accidental childhood poisoning. A federal regulation requires special safety closures (child-proof caps) for aspirin containers.

[Taken from FDA Consumer Memo (FDA) 72-3002]

A Primer On MEDICINES

FDA's Role

FDA is the Federal agency responsible for reviewing all drugs for safety and effectiveness and for seeing that they are made correctly and labeled properly. To fulfill its responsibilities, FDA:

- approves all new drugs before they can be marketed
- decides whether a new drug should be sold OTC or only by prescription
- seeks to remove from sale any drug that is unsafe, ineffective, improperly made, or incorrectly labeled
- tests all batches of insulin, vaccines, and antibiotics before they are shipped to pharmacies
- inspects manufacturing plants for sanitary conditions and proper manufacturing practices.

You Can Help

Sometimes after buying a medicine you notice that it seems off-color or stale. Don't use it. Return it to the pharmacy. If you believe a medicine has gone bad or is otherwise harmful, don't just toss it out—report it to FDA.

Call or write your nearest FDA field office or resident inspection station. You can find the address by looking in the phone book under U.S. Government; Department of Health, Education, and Welfare; Food and Drug Administration. If you wish, you can write directly to FDA headquarters at 5600 Fishers Lane, Rockville, Maryland 20852.

What to do:

1. Report your problem promptly, giving your name, address, and phone number.
2. State clearly what appears to be wrong.
3. List any information stated on the label and give any code numbers that appear on the container.
4. Give the name and address of the store where the article was bought and the date of purchase.
5. Save whatever remains of the product for possible examination by the FDA.
6. Hold any unopened container of the product bought at the same time.

Choosing a Pharmacy

When you have to get a medicine immediately—for a child running a high fever, for example—you'll want to go to the nearest, quickest pharmacy.

When, however, you will be using the same prescription medicine for a long time, you may be able to save money by shopping comparatively—that is, checking various stores to find the lowest price.

Generally, pharmacists who give more services charge higher prices than those providing fewer services. Since prices do vary, it is to your advantage to take time to shop comparatively before you select the pharmacy where you will buy most of your medicines.

You may prefer to use one pharmacy almost all the time. In choosing a pharmacy, you should look for one which keeps a record of all the prescriptions filled for you and your family. (These records or personal drug histories help the pharmacist spot undesirable combinations of medicines that you and your doctor may not be aware of.)

Before leaving the pharmacy, look at the label on the prescription medicine you've received. The following information should be on it:

- the pharmacy's name, address, and phone number
- the prescription number
- the patient's name
- how often and when to take the drug
- how much to take each time
- special instructions (refrigerate, shake well, etc.)
- the doctor's name
- the date the prescription was filled
- the name of the drug (if the doctor says it should be put on the label).

If any of this information is not on the label or if you think any of it is wrong, ask the pharmacist. If you're still not sure, call your doctor. Write in the new date on refills; the pharmacist uses the date the prescription was first filled.

SELF-MEDICATION

Self-medication is the act of treating oneself with non-prescription medications, known as over-the-counter (OTC) drugs, to obtain relief from minor medical problems (headaches, indigestion, constipation, mild aches and pains, skin irritations, etc.).

Occasionally, one may medicate oneself with a prescription drug borrowed from another individual, a procedure *not* recommended by the medical profession due to the danger of developing serious side effects. Self-medication has its limitations. Symptoms that persist require the attention of a physician for proper diagnosis and treatment. Prolonged self-medication can lead to serious consequences.

Drug Action and the Body's Reaction

At the same time a drug is acting on some function or part of the body, the human body is doing something to the drug. Normally, the body will limit the drug's duration of action and effectiveness and then excrete it. This normal function, called "detoxification," requires the proper performance of organs such as the liver, kidney, or lungs.

If an individual cannot detoxify the drug—because his body is not reacting properly, because he has taken too much medication, or because of other complications—the drug's action may be much more prolonged and severe than desired. Some drugs act by interfering with normal body functions, which must be restored to normal after the drug is stopped. If the misuse of drugs disturbs the delicate balance of the body's chemistry, the restoration of normal functions may be impeded.

Overuse of Drugs

OTC drugs are safe in the recommended dosage, but they may be extremely dangerous in large overdoses. For example, aspirin is seldom thought of as dangerous; we reach for it routinely to soothe headache and other pains. But there are many reports of poisonings of young children who swallow more aspirin than their little bodies can handle.

In adults, continued, excessive use of some pain-killing drugs has been found to cause severe and irreversible kidney damage. Some drugs for relief of stomach upsets can aggravate the condition by causing an imbalance in the body's secretion of enzymes while other indigestion remedies contain bromide which can accumulate to a toxic level in the blood, causing bromide poisoning. Over-medication of symptoms, such as continued use of laxatives to relieve constipation, may mask the underlying cause. Constipation may be a warning of a condition that requires prompt and professional medical or surgical attention.

Combining Drugs

The combined effect of two or more drugs on the body can be very different from the action of each drug taken separately. Sometimes combining drugs can produce dangerous—even fatal—reactions. This is because each drug not only acts on the body, but may act upon and increase the effect of other drugs . . . a condition known as "potentiation."

For example, aspirin increases the "blood-thinning" effect of an anti-coagulant. For that reason, a patient with heart disease who has been taking an anti-coagulant under his doctor's supervision may risk the serious complication of hemorrhage if he uses aspirin whenever he gets a headache. Patients who regularly take a prescription medication should seek and follow the doctor's advice in using OTC drugs.

Alcohol is another substance that can increase the effect of a drug. Hypnotic drugs, such as sleeping pills and antihistamines, are examples of drugs that interact with alcohol, producing potentially harmful results. Again, patients should seek professional guidance before combining alcohol with either prescription or OTC drugs.

The Responsibility of the Individual

The hazards of self-medication result from carelessness, faulty self-diagnosis, and failure to heed the warnings and directions for use of the drug. The Food and Drug Administration enforces the law to protect you, but you can be your own best protection against harmful effects of self-medication. Follow these simple rules for your own safety:

Don't be casual about taking drugs.

Don't take drugs you don't need.

Don't overbuy and keep drugs for long periods of time.

Don't combine drugs carelessly.

Don't continue taking OTC drugs if symptoms persist.

Don't take prescription drugs not prescribed specifically for you.

Do read and follow directions for use.

Do be cautious when using a drug for the first time.

Do dispose of old prescription drugs and outdated OTC medications.

Do seek professional advice before combining drugs.

Do seek professional advice when symptoms persist or return.

Do get medical check-ups regularly.

Excerpts from "Self-Medication", DHEW Publication No.(FDA) 73-3025

Two Types of Medicines

There are two basic types of medicines: over-the-counter (OTC) drugs and prescription (Rx) drugs.

Prescription drugs (which bear the symbol Rx) can be ordered or prescribed only by a doctor and can be sold only by a registered pharmacist. Generally more powerful than OTC medicines, prescription drugs are also more likely to cause side effects.

Over-the-counter medicines (also known as home remedies and patent medicines) include such common remedies as aspirin, laxatives, and antacids. If used according to the directions on the label, they are relatively safe. You can buy OTC medicines without a prescription in any drugstore and in many supermarkets and other stores.

How to Buy Prescription Medicines

When you see your doctor, tell him everything he should know about you—such as allergies and unpleasant past experience with medicines. Don't expect to receive medicine every time you see your doctor; often he will not find it necessary to give you any. When he does give you a prescription, be sure you have the answers to these questions:

- *What is the name of the drug?* Write it down for your own records. You may need to refer to it later.
- *When and how often should it be taken?* If, for example, he tells you to take the drug three times a day, be sure to note whether it should be taken before or after meals. It could make a difference. Some drugs taken on an empty stomach may cause upset. Others should be taken *only* on an empty stomach.
- *Can the least expensive form of the medicine be prescribed?* Often the doctor can write the prescription by using the "generic" or official name of the medicine rather than a specific brand name. This may save you money at the pharmacy. He may, however, prefer to prescribe by brand name the drug which has worked best in his experience.
- *Can the new medicine be taken along with others?* If you're taking other medicines, let the doctor know.
- *What reactions may I expect?* In some people, medicines may cause drowsiness, nausea, vomiting, dizziness, nervousness, or other reactions.
- *What precautions should I take?* For example, if the expected reaction to a medicine is drowsiness, dizziness, or unsteadiness, you shouldn't drive or operate machinery.
- *Can this prescription be refilled?* If the medicine is to be taken frequently, ask if you can refill the prescription as needed. The doctor may want you to check with him by phone or come in before continuing the medication. He may allow refills, but only a specified number.
- *Must I finish the bottle?* Before you leave the doctor, be sure he has told you how long to take the medicine and whether to check with him within a certain time.

If, after leaving the doctor's office, you have more questions or have forgotten some of the answers, don't hesitate to call him.

How to Buy OTC Medicines

Before you buy any OTC drug, ask yourself first whether you really need it. Have you been convinced by a TV commercial, a friendly neighbor, or an article in a magazine or newspaper? For instance, if you feel tired, do you need stimulants or more sleep? Should you see your doctor?

If you do need an OTC medicine, you should read the labels and ask your pharmacist's advice.

Federal law requires that the following information be on all OTC drug labels:

- Name of the product, and the name and address of the manufacturer, packer, or distributor.
- The active ingredients. This information helps people with sensitivities or allergies avoid products which cause bad reactions. Many OTC medicines contain exactly the same ingredients and differ from each other only in brand name. By checking ingredients, you can avoid buying identical medicines, thereby saving money and guarding against taking an overdose.
- Directions for safe use.
- Cautions or warnings. These tell you what side effects might occur and which people should not take the drug at all. Sometimes they warn against driving or operating machinery after taking the drug. Labels may also warn you not to take the medicine for too long without consulting your doctor. A typical warning reads: "If symptoms persist more than 24 hours, see your doctor."

Pharmacists are well-trained professionals who can help their customers understand how to buy and use drugs.

Your pharmacist can answer your questions about the labels on drugs and may be able to help you select a lower-priced brand of drug than the one you would have chosen by yourself.

Don't be reluctant to ask for help. Remember that your health may be at stake.

To avoid some common pitfalls in buying OTC drugs, keep these thoughts in mind:

- Pills, gadgets, and wishful thinking seldom help you lose weight. Instead, eat fewer calories and exercise regularly. Your doctor can help you plan a program for losing weight.
- Most people don't need vitamin pills. A varied diet provides the vitamins and minerals most people need.
- If your doctor does recommend vitamins, take only the suggested amount—no more. Large doses of certain vitamins, taken often, can have a toxic effect.

Some Facts About Medicines

You shouldn't always reach for some medicine when you don't feel good. Sometimes ads or commercials for OTC medicines may persuade you to take medicines, although you'll do as well to let time and your body do the healing.

- Many Rx and OTC medicines relieve symptoms without actually curing illness. For example, cold remedies may make you feel more comfortable by reducing sniffles and sneezes, but the cold will last as long as it would with no medicine at all. If symptoms such as pain, fever, or headache persist, see a doctor.
- All medicines affect body functions. OTC medicines generally affect you less than Rx drugs because they are less powerful.
- A medicine that is safe and effective for most people may cause problems for others who have unpleasant or allergic reactions to certain medicines. For example, some persons get a skin rash if they take aspirin.
- Certain medicines cannot safely be taken together. Some Rx drugs for infections, for example, cannot be taken with certain OTC drugs for acid indigestion.
- Many medicines lose or increase their strength as time goes by. Therefore, the large economy size may not be economical if it stands unused for a long time. However, if the doctor prescribes a drug you must take regularly and you can save money by buying a large quantity, ask your doctor or pharmacist how long it will keep.

Using and Storing Medicines

Directions. Continue taking an Rx drug for the entire time ordered by your doctor, even if you're feeling better. You might prevent the drug from doing a complete job and find yourself sick again. With both Rx and OTC medicines, follow very carefully the directions about when and how much to take. Ask your pharmacist for help if you need it.

Side effects. Bear in mind that sometimes certain people react adversely to a particular medicine. If you find that an Rx drug causes a side effect—perhaps a rash, headache, nausea, or dizziness—talk to your doctor. Your pharmacist can help too. The drug may be discontinued, the dose changed, or another drug substituted.

Combining drugs. Consult your doctor or pharmacist before you take two drugs together. If you're taking any medicines at all, don't drink alcohol without first asking your doctor. It could be dangerous.

Storing medicines. Always read the labels on both OTC and Rx drugs for special storage instructions. Some medicines should *not* be kept in the bathroom medicine cabinet. If the label says, "Keep in a cool, dry place," the bathroom will be too warm and steamy. Some drugs must be stored in the refrigerator.

Clean out your medicine chest regularly. Throw out old medicines, particularly Rx drugs. If your doctor takes you off a medicine before it's used up, destroy what's left.

Pill boxes are only for temporary storage. Drugs carried in pill boxes for a long time may lose their strength or become too strong. Some pills, such as nitroglycerin, should never be carried in pill boxes. They should be kept in the pharmacy's container, which is especially designed to maintain their strength.

Labels. Be sure to keep the label on or in the container. You need it to identify the medicine and also to refer to the directions. When pouring liquid medicines, keep the label side on top so the liquid won't pour down the side and blot out the print.

Sharing drugs. An Rx drug is prescribed for you and you alone. Never let anyone else take it, even if his symptoms seem to be the same as yours. The other person might not have the same illness, could be allergic to the drug, or could have a bad reaction.

Look-alikes. Always read the label before you take a medicine—bottles and drugs often look the same. Never take medicines in the dark.

When you're traveling. If you need to take prescription medicines with you on a long trip, be sure you have enough. Carry them in the original, labeled containers. Pharmacists often do not fill prescriptions written by out-of-State doctors. In an emergency, you can contact a hospital. If you move to another city or State, take enough medicine to last until you find a new doctor. Arrange for your medical record to be forwarded to your new doctor.

Precautions for children. Medicines cause more accidental poisonings among children under 5 than any other chemicals. Therefore, the law requires that most OTC and Rx drugs, as well as many other potentially dangerous chemicals, be packaged so that only adults can open them.

Always buy safety packaging if you have children or if children visit your home. Be sure to close the bottles properly after each use. Store all medicines out of a child's reach; it is all too easy for a tot to climb from the toilet to the sink to the medicine chest. One sure way to keep poisonous products away from children is to have one locked cabinet for medicines and other potentially dangerous chemicals.

Be sure not to leave medicine out when you answer the telephone or the door. Put it away first or take it with you. It only takes a moment for a child to swallow an overdose.

When you give your children medicine, never refer to it as "candy" or something else they like. They may try to get more of it when they are alone.

Make sure you always give your children exactly the right amount of medicine. Some OTC drugs should never be given to children; others are especially designed for them. Read the labels carefully, and consult your pharmacist or doctor if you have questions.

Excerpts from FDA Consumer, December 1973/January 1974.

A MINI LESSON FROM FDA

RADIOLOGICAL HEALTH

Topic: Non-Diagnostic Radiation Safety

Level: Middle and Upper Grades

Objective: The students will indicate an awareness of sources of and protection from radiation exposure in their world.

Skills: Research, comparisons, and interviewing

Materials: Student reading: "Radiation Exposure - A Balance Scale."

Procedure:

1. Discuss possible sources of radiation in our environment, artificial and natural; i.e., microwave ovens, color TV sets, and radiation from uranium and thorium in the soil. Students who are interested should research and report to the class on each of these.

2. Survey the class to determine how many have seen or used a microwave oven, or eaten food from one. Those ovens often found in canteens, snack shops, etc. used for quickly warming up foods or sandwiches are microwave ovens.

3. When students have gathered information on these sources of radiation, have them read "Radiation Exposure - A Balance Scale," and use the risk-benefit principle as it applies to these non-diagnostic uses of radiation.

Follow Up:

1. Visit an appliance store to talk about and gather consumer information on:

   (a) Color TV receivers
   (b) Microwave ovens
   (c) New electronic devices such as ultrasonic dishwashers

2. Find the certification label on color TV sets and microwave ovens.

3. Contact the state or local public health departments to determine how the electronic equipment is regulated.

4. Interview your neighbors about their understandings about radiation.

Code for test answers on page 2: a) false b) false c) true d) false

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Evaluation: Use the following for testing or discussion

1. Discuss student observations of the use of microwave ovens in canteens and snack shops.

   (a) Were instructions to the user on the microwave ovens posted?

   (b) If no instructions were posted, was the microwave oven being used properly?

   (c) Was a telephone number to call for service or maintenance posted?

   (d) Did the microwave oven users assure proper oven operation by following these few simple precautions? Safety tips are:

   DO
   -- Follow manufacturer's recommended instructions for operating procedures.

   -- Switch the oven off before opening the door.

   -- Report immediately to a qualified serviceman, damage, tampering, or spilled food.

   DO NOT
   -- Insert objects through the door grill or around the door seal.

   -- Tamper with or inactivate the oven safety interlocks.

   -- Leave the oven with spilled food.

2. True-False Statements

   _____ (a) Microwave ovens are not safe to use.

   _____ (b) Sitting too close to a color TV set is dangerous.

   _____ (c) People are constantly being exposed to radiation.

   _____ (d) Use of radiation-producing equipment should be prohibited.

Reference:
"Radiation Exposure - A Balanced Scale" (attached)

RADIATION EXPOSURE - A BALANCE SCALE[1]

All of us have used a teeter-totter and most of us have used a balance scale at some time. We know that on a teeter-totter or a balance scale, one side must be balanced against the other side to keep it level. The mid-point on which the scale rests is called the fulcrum. The balance scale idea can be used to explain a difficult principle used by the Food and Drug Administration to help people understand about the dangers of radiation. It is called the risk-benefit principle. A radiation exposure scale has risks on one side and benefits on the other. In the middle are the things which help to balance risks against benefits.

Radiation Risks

Radiation is a form of energy. It can come from many sources including x-ray machines, fast cooking microwave ovens, and even from color TV sets. Radiation is dangerous and there are risks to health from being exposed to it. For example, most people know that one of the dangers of long exposure to great amounts of radiation can cause leukemia and other forms of cancer. It can also damage people in such a way, that if they become parents, their children could be born defective. X-ray machines must give off some radiation, but the risk to health can be reduced if the amount of radiation is as small as possible and if it is used only when necessary.

Microwave ovens can be totally safe if they are manufactured and used properly. As we shall see, the manufacturer is watched by the FDA, but the user is not. If a microwave oven is damaged, or if the door is not closed tightly, microwaves can leak out and they can cause damage to body organs. Experiments with test animals have shown that microwaves can cause cataracts of the eye. The manufacturing of color TV sets is regulated as well. There now seems to be no danger of radiation from color TV's sold, since implementation of the Radiation Control for Health and Safety Act of 1968.

Radiation Benefits

To see what is on the other side of the scale, we must look at the benefits of x ray. The dentist can use x ray to find tooth decay and other dental problems which he cannot otherwise see. A doctor can diagnose disease, broken bones, suspected tumors, and other serious physical conditions difficult to identify and treat without "seeing" them.

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[1]Robert T. DeVore, "Diagnostic X Rays: How Safe are They," FDA Consumer, (June, 1973), pp. 4-7.

Microwave ovens may bring great changes in home cooking. With a microwave oven, a potato can be baked in minutes rather than one hour. There are many more benefits of using radiation, but these few should help you understand its importance.

Balancing the Scale

The most important part of our radiation exposure balance scale is that middle part, the fulcrum. This fulcrum uses people, laws, and regulations to help balance the risks against benefits of radiation.

The people who can help lower the risk from radiation, are doctors, dentists, x-ray technologists, and you. Doctors, dentists, and x-ray technologists should use x ray only when necessary. Citizens like you can lower the risk by following some simple rules.

1. Let the doctor decide when you need x ray; do not demand it when he does not prescribe it.

2. Keep records of x rays you have had.

3. Ask for protective shielding when being x-rayed.

When using a microwave oven, be sure to follow the manufacturer's directions, and only use it when the door is closed tight. Also, keep the door seals clean.

Radiation is one of the most unusual agents over which FDA has responsibility. Radiation cannot be seen. Used properly, it contributes substantially to man's welfare. Used inappropriately, it can create serious risks to human health. The legislative responsibility for electronic product radiation control, as well as the responsibility for improving protection in the use of radiation and radioactive materials, rests with the Bureau of Radiological Health. This Bureau covers a wide range of subjects such as:

-- Radiation hazards.
-- Possible genetic effects of x rays.
-- Diagnostic x-ray equipment.
-- Microwave ovens.
-- Color television receivers.
-- Industrial radiation.
-- What consumers can do to help improve radiation protection.

A MINI LESSON FROM FDA

COSMETICS

Topic: New Regulations on Cosmetic Products.

Level: Middle and Upper Grades

Objective: The student will be able to:

1. Define cosmetics in his own words.
2. Identify cosmetic-like products which are regulated as a drug.
3. Understand, in general terms, the FDA cosmetic ingredient label regulation.

Skills: Summarizing, classifying, observing, and listening.

Materials: Two student readings:

1. "A Revolution in Cosmetic Label Regulations"
2. "What's a Cosmetic?"

Procedure:

1. Read to the students, "A Revolution in Cosmetic Label Regulations." Have them summarize the article.
2. Regulations - If the class has studied FDA food labeling, have the students compare and contrast cosmetic and food labeling regulations.
3. List cosmetic products - Have the students brainstorm for names of specific cosmetic products which are familiar to them from their home, from TV commercials, and other advertising. If they are having trouble identifying products, think about various uses of cosmetics. Record the list of products on the chalkboard or on the overhead projector.
4. Classifying - After a long list of cosmetic products has been Prepared:
   a) Jointly work out a classification scheme which will include all items. One obvious classification is based on the purpose of the cosmetic.
   b) Place the named products in the classification categories.

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5. Read to the students, "What is a Cosmetic?" Note that the term "active ingredients" on the label indicates that the product is a drug. After listening to the article, have them:

   a) Rephrase the definition of cosmetics into their own words.

   b) Explain why some cosmetic-like products are actually drugs.

   c) Review the list to determine if any of the products are actually drugs.

Follow Up:

1. Have the students read cosmetic labels.

2. Compare warnings and caution information.

3. As companies change over to comply with the new ingredients labeling regulations, have the children report on the appearance of the new labels.

Evaluation: Use for testing or discussion.

1. Write a definition of a cosmetic.

2. Select and discuss the correct answer.

   A. The FDA requires that all cosmetic products:

      (1) Make you beautiful.
      (2) Show on their label the ingredients contained in the product.
      (3) Can only be sold in drugstores.
      (4) Have the term "active ingredients."

   B. The term "active ingredient" on a product means that it is:

      (1) Not to be put in the eyes.
      (2) A drug.
      (3) Harmful.
      (4) Not for use on people.

References: The two student readings attached are condensed from the articles:

"An Overview of Cosmetic Regulations," FDA Consumer, April, 1972.

"We want you to know about cosmetics," DHEW Publication No. (FDA) 74-5004.

"A Revolution in Cosmetic Regulations," FDA Consumer, April, 1974.

"A REVOLUTION IN COSMETIC LABEL REGULATIONS"

Your introduction to cosmetics came the first time your Mother used baby powder on you. And today, if you use toothpaste, shampoo, perfume, or any of the more than 80 other types of products considered by the Food and Drug Administration to be cosmetics, you ought to know about the new regulations proposed by FDA.

These regulations will require that ingredients be listed on cosmetic labels. This will bring consumers more information about what they purchase and will enable them to make value comparisons among cosmetic products.

Wheat flour, sassafras oil, and slippery elm bark may play more of a role in your life than you'd suspect. The same is true of chocolate oil, stearic acid, glycerin, simethicone disodium EDTA, and any of about 5,000 other ingredients used in cosmetics for men, women, and children. You've used many of these. In the proposed regulation you would no longer have to wonder just what it is you're splashing, dabbing, rubbing, brushing, massaging, or smoothing onto your body to improve your appearance. Cosmetics sold in this country would have to list the ingredients on the label. The ingredient that is present in the largest amount would be listed first and so on down the list.

For some consumers, a look at what goes into their cosmetics will be merely interesting. Some will find such novelties, for instance, as mistletoe, gold, silver, copper powder, tall oil, shark liver oil, and dandelion root, just to name a few attention-getters.

But the proposed regulation was not developed merely to satisfy consumer curiosity. It was issued under authority of the Fair Packaging and Labeling Act, which was passed by Congress to help consumers make value comparisons and to prevent deception. It should be particularly helpful to consumers who are allergic to certain ingredients. After a doctor determines what is causing the allergy, the consumer would be able to avoid the irritating substance by reading the labels of cosmetics.

Use Cosmetics With Care

Cosmetics are generally safe if used according to the instructions on the label. But cosmetics, like any other product, can be harmful if not used properly.

Here are a few safety rules to remember when you're using cosmetics:

1. Before using any cosmetic, read the label carefully and follow directions exactly. This is especially important when using antiperspirants, depilatory (hair-removing) preparations, hair dyes and colors, home permanents, skin packs.

2. To determine whether you are allergic to a cosmetic, apply a small amount on the inside of your forearm. Leave it for 24 hours. If you see any adverse effect (such as redness, blisters), don't use it again. In the case of hair preparations, do a "patch test"—using it as directed on one small area of the hair and scalp, to see whether there is an adverse reaction—before using it for the entire area.

3. If a cosmetic causes any adverse effect—burning, "breaking out," stinging, or itching—stop using it. If the condition appears serious, see yourdoctor. And to speed diagnosis, take with you the cosmetic you suspect has caused the problem.

4. Wash your hands before applying a cosmetic. This prevents contamination from your hands spreading to the cosmetic and also possibly to a sensitive part of your body.

5. Close containers after each use to prevent contamination. Many bacteria grow more rapidly when exposed.

6. Never borrow another person's cosmetics. You may be borrowing a contaminated cosmetic. There is no way to tell just by looking whether a cosmetic is contaminated.

7. When water must be added to a cosmetic before it can be used-such as cake eyeliner—it's a dangerous practice to substitute water with saliva. Some people actually spit into their cosmetics! Germs in saliva grow rapidly in new environments outside the mouth.

8. Don't expect a product to do the impossible. For instance, a sunscreen preparation cannot protect you indefinitely from harmful effects of the sun. Even if you do not burn, you can become quite sick from overexposure to the sun.

9. Remember that no product is foolproof against allergies. "Hypoallergenic" means there is less likelihood to allergic reaction, but there is no way to formulate a product to which someone, somewhere may not be allergic.

10. Don't expect a cosmetic to cure a skin disease. While medicated cosmetics may help control certain problems, your best bet is a physician's advice and proper medication.

11. Aerosol products should be used as directed on the label, in well-ventilated rooms to avoid inhalation. As with other products, follow exactly all directions and warnings.

12. Don't allow children to play for unusually long periods (longer than a normal bath time) in bubble baths. Although bubble baths have been reformulated to be less irritating, some ingredients used to form voluminous bubbles are more irritating than soap. Follow directions exactly on amounts of the product to be used. It may be wise to rinse children off after they have been bathed in bubble bath.

13. When you plan to be out in direct summer sun, you are wise not to use colognes, perfumes, or aftershaves. This can make your skin particularly light-sensitive in the applied areas and lead to splotching and irritation.

14. Be extremely cautious when using cosmetics around the eyes. Use only those labeled for use in eye areas and be sure the products are kept clean and covered. If irritation developes, see a physician immediately.

15. Keep cosmetics away from children. Unsteady hands, sensitive skin, and creative minds can cause injury.

In taking action against a cosmetic, FDA must first decide whether the product is by law a cosmetic, or whether it actually is a drug.

What You Can Do

If you have any complaints about cosmetics—if you believe the labeling is wrong, or if you have an adverse reaction—report it to the manufacturers and to FDA. Send your complaints to:

Food and Drug Administration
Division of Cosmetics Technology,HFF-430
200 C Street, S.W.
Washington, D.C. 20204

Ingredient labeling can be meaningful in preventing consumer deception by precluding product claims that are unreasonable in relation to the ingredients present and by providing consumers with additional information that can contribute to a knowledgeable judgment regarding the reasonableness of the price of the product.

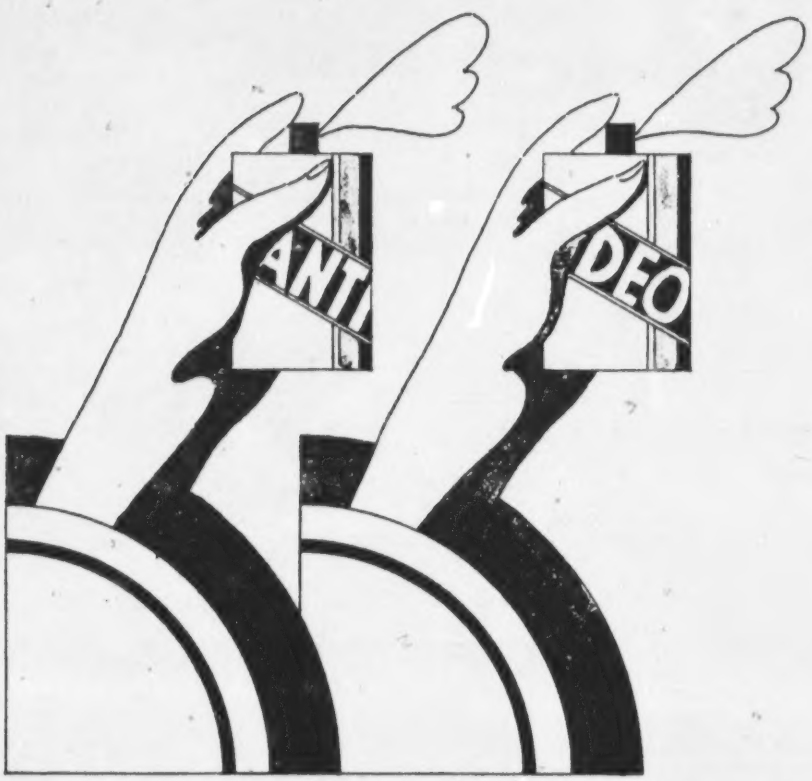
"What is sodium laureth sulfate and what's it doing in a cosmetic?" This is just one possible question consumers are going to ask after seeing cosmetic ingredients labeled.

A lot of unfamiliar chemical terms are going to be on cosmetic labels. Consumers won't know what some of them mean--let alone be able to pronounce them. It should provide a real field day for chemistry majors, but how will most consumers use the labeling?

First, people with allergies, if they see their doctor, will know which ingredients they should avoid. To them certain words--no matter how long--will quickly come to mean something.

Other consumers may decide to ask the manufacturer or FDA what general purpose a certain ingredient serves. (By the way, sodium laureth sulfate is a cleaning and foaming agent for shampoos.)

Most persons will become familiar with types of ingredients which are common to certain product categories simply by repetition--routine shopping and comparisons. Because FDA has provided for standardizing a name for each ingredient, there is no possibility that one ingredient can be masquerading under different names from one product to another. (Lanolin oil, for instance, will always go by the name "Lanolin Oil," rather than by 15 other names that had been used among the trade for that ingredient.) All manufacturers will have to use the same names for ingredients.



WHAT'S A COSMETIC?

According to the Federal Food, Drug, and Cosmetic Act, cosmetics are defined as:

1) Articles intended
   -- to be rubbed, poured, sprinkled, or sprayed on,
   -- introduced into, or
   -- otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or
   -- altering the appearance, and

2) Articles intended for use as a component of any such articles; except that such term shall not include soap.

However, cosmetics are also regulated as drugs when they make any claim to alter a body function. Example:

   -- a deodorant is regulated as a cosmetic, because it is intended only to prevent odor; but
   -- an anti-perspirant is regulated as a drug because it is intended to actually reduce perspiration, which is a normal body function.

If a cosmetic is also considered a drug, the drug ingredients must be listed before all other ingredients and follow the term "active ingredients." You will find this, for instance, on dandruff shampoos, some toothpaste, anti-perspirants, sunscreen products, and on all medicated cosmetics.

A MINI LESSON FROM FDA

A REPORT TO FDA

Topic: Business letter to FDA.

Level: Middle and Upper Grades

Objective: The student will rewrite a business letter. He will prepare a letter, brief and to the point, using proper punctuation and form.

The student will realize that he has the opportunity to report harmful products to the FDA or other appropriate consumer protection agencies.

Skills: Letter writing, reference.

Materials:

- Jimmy Jones letter to FDA (use instant ditto to duplicate) (page 3)
- FDA CONSUMER Memo, "How You Can Report to FDA" (page 4)
- Reply from FDA District Director of Compliance Branch (page 6)

Procedure:

1. Provide each student with Jimmy's letter to FDA.
2. Post on the bulletin board a copy of "How You Can Report to FDA."
3. Have the students use the space between lines to correct errors, such as--
   a) eliminate useless -- words, phrases, sentences.
   b) make changes in -- wording, punctuation, form.
4. Have the class check the local telephone directory for an "FDA" address.
   Look under:
   a) U.S. Government,
   b) Department of Health, Education, and Welfare,
   c) Food and Drug Administration (FDA)
5. Have students re-write the letter from Jimmy Jones.
6. Share FDA's reply to Jimmy with the class. Read to the class and post on bulletin board.

Code: Test answers - page 2 (1-d; 2-b; 3-a, c, d, e, g, j, l)

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7. Discuss other harmful products which could or should be reported to FDA or other consumer protection agencies. If there is no local FDA office, determine which agency could help a consumer.

Follow Up:

1. Students practice skills in other writing exercises.

2. Students make reference to their responsibility to report harmful products to consumer protection agencies.

3. Students seek information by writing letters to manufacturers or government agencies. They share their replies with the class.

Evaluation:

Use the following for testing or discussion:

1. Which of these should a consumer contact if he buys an insanitary package of fresh ground beef?

   ___ (a) The President

   ___ (b) The Food and Drug Administration

   ___ (c) Better Business Bureau

   ___ (d) United States Department of Agriculture (USDA)

2. In a business letter to the FDA, which sentence is best:

   ___ (a) I went with my Mother to buy some eggs, milk, tuna fish and bread.

   ___ (b) Yesterday I bought a can of tuna fish that was spoiled.

   ___ (c) I saw a can of tuna fish at the store but it was spoiled.

   ___ (d) I went to the store but forgot to buy tuna fish so I had to go back later.

3. Check the unsafe or unwholesome products you should report to the Food and Drug Administration:

   ___ (a) peanut butter
   ___ (b) baby bed
   ___ (c) aspirin
   ___ (d) microwave ovens
   ___ (e) suntan lotion
   ___ (f) doll
   ___ (g) vaccine
   ___ (h) infant sleepwear
   ___ (i) round steak
   ___ (j) candy bar
   ___ (k) bicycle
   ___ (l) cereal

126 Clearview Rd.
Greentown, Md. 20853
December 9, 1974

Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Dear Sir:

Yesterday, at 12:00 pm, I went to the store for my Mother and bought a can of green beans, a half gallon of milk, and a package of macaroni. When I got home I noticed that the can of green beans was buldging. Because we learned about botulism last week in school, I am worried that this can of green beans and others like it maybe harmful.

The brand name is Sombrero, and it is produced by Beanstalk Product Incorporated, Houston, Texas. It has these numbers on the lid: HU576-212-8162. The store where I bought it is just down the street from my house at 216 Clearview Rd. It is called Johnson's Market. I have told Mr. Johnson about the bulging can of green beans and I returned the unopened can to him.

How will the FDA check to make sure that other cans goods from the same company are safe and will not poison anyone?

Thank you.

Sincerely,

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Jimmy Jones

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

District Office
900 Madison Avenue
Balitmore, Maryland 21201

December 12, 1974

Mr. Jimmy Jones
126 Clearview Road
Greentown, Maryland 20853

Dear Jimmy:

The letter which you sent to the Food and Drug Administration headquarters office has been referred to the Baltimore District Office which serves your city. I want to thank you for your prompt action in notifying both the store and FDA when you found a bulging can of green beans. Such prompt action can often help FDA in removing harmful or defective products from the market. Your letter contains all of the information we need to start an investigation.

In your letter you ask for a description of what we will do as a result of your complaint. The steps in an FDA investigation fall into three kinds of actions. First, we will visit the store in an effort to locate all of the cans with this code. Usually this leads us to a warehouse and other stores which sell this product. Second, we will collect cans with this code and other samples of suspicious looking cans. Third, and at the same time, other investigators will visit the manufacturer to find out if there are problems in the food processing plant.

Consumers often help us in our job of protecting people. By your actions you have joined those efforts. Please accept my thanks.

Should you have further questions related to the products that FDA regulates, or should you wish FDA publications address your letter of inquiry to the District Office which serves your geographic area.

Sincerely,

WILLIAM C. WHITE
Director, Compliance Branch

FDA

Consumer MEMO

CURRENT AND USEFUL INFORMATION FROM THE FOOD AND DRUG ADMINISTRATION

HOW YOU CAN REPORT TO FDA

If you come across a food, drug, medical device or cosmetic that you believe may be mislabeled, insanitary, or otherwise harmful, you will perform a public service by reporting it to the Food and Drug Administration.

The information you supply to FDA can and often does lead to detection and correction of a violation. Many products have been recalled or removed from the market because of action initiated by a consumer.

FDA can't take legal action solely on the basis of your complaint, of course. But it will investigate promptly, in accordance with the requirements of the law. And if a hazard is found, FDA will seek to remedy the situation within the bounds of the law.

Here are some guidelines to follow in reporting hazards to FDA.

BEFORE YOU REPORT

Before you report to FDA about the possible hazards of a product, ask yourself these questions:

- Have I used the product as labeled?
- Did I follow the instructions carefully?
- Did an allergy contribute toward the bad effect?
- Was the product old when I opened it?

Make sure you've taken all these factors into consideration before you report a possible hazard to FDA. The hazard may lie in improper use of a product rather than in an inherent defect.

With a medicine, for example, you may suspect the product is harmful if you experience an unusual reaction. You should report this to your doctor immediately.

But the reaction may be a "side effect" rather than an indication of a defect. It may not be necessary to inform FDA about it. Your physician will be the best guide.

WHERE TO REPORT

You may refer your complaint in writing or by phone to the nearest FDA Field office or resident inspection station.

FDA has 10 Regional offices, 19 District offices, and 97 resident inspection stations throughout the United States. You can find the address and phone number of the nearest FDA office in the telephone directory under U.S. Government, Department of Health, Education, and Welfare, Food and Drug Administration.

If you wish, you may write about your complaint directly to FDA headquarters. **The address is Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852.** The complaint will reach the correct person.

HOW TO REPORT

Report your grievance as soon as possible after it occurs. Give your name, address, telephone number, and directions on how to get to your home or place of business.

State clearly what appears to be wrong.

Describe in as much detail as possible the label of the product. Give any code marks that appear on the container. For example, markings on canned foods are usually embossed or stamped on the lid.

Give the name and address of the store where the article was bought, and the date of purchase.

Save whatever remains of the suspect product or the empty container for your doctor's guidance or possible examination by FDA.

Retain any unopened containers of the product you bought at the same time.

If an injury is involved, see your physician at once.

Report the suspect product to the manufacturer, packer, or distributor shown on the label, and to the store where you bought it.

FDA has limited jurisdiction over certain consumer products. If you have complaints about any of the following, these are the Federal agencies to inform:

- Suspected false advertising—*Federal Trade Commission.*
- Meat and poultry products—*U.S. Department of Agriculture.*
- Sanitation of restaurants—*local health authorities.*
- Products made and sold exclusively within a State—*local or State Health Department or similar law enforcement agency.*
- Suspected illegal sale of narcotics or dangerous drugs (such as stimulants, depressants, and hallucinogens)—*Drug Enforcement Administration, U.S. Department of Justice.*
- Unsolicited products by mail—*U.S. Postal Service.*
- Accidental poisonings—*Poison Control Centers.*
- Dispensing practices of pharmacists and drug prices—*State Board of Pharmacy.*
- Pesticides, air and water pollution—*Environmental Protection Agency.*
- Hazardous household products and toys—*Consumer Product Safety Commission.*

DHEW Publication No. (FDA) 74-1001

Today's FDA

The food you buy in a supermarket. Is it safe?

The nonprescription medicine you buy in your drug store. Does it work?

The color TV you have in your living room. Does it give off too much radiation?

These are some of the issues that people today are concerned about.

And these are the issues that the Food and Drug Administration deals with every day.

FDA is on the job, every day, carrying out its responsibilities on behalf of the American public, to assure that foods are safe, that medicines do work, that color TVs are safe. And more. Virtually every product you see in a supermarket or drug store is regulated by FDA.

Here are some facts about FDA, its activities, and how they relate to your personal safety in today's complex marketplace.

What FDA does

FDA performs hundreds of activities to help the public and to protect consumers. Some of these activities are:

- FDA inspects plants where foods, drugs, cosmetics or other products are made or stored to make sure good practices are being observed.
- FDA reviews and approves new drug applications and food additive petitions before new drugs or new food additives can be used.
- FDA approves every batch of insulin and antibiotics, and most color additives before they can be used.
- FDA sets standards for consumer products, such as foods that are made according to a set recipe (peanut butter, for example). FDA tests products to assure they meet Government standards.
- FDA is conducting a review of all prescription and non-prescription medicines, biological drugs and veterinary drugs now on the market. The goal is to make sure they are safe, effective and properly labeled.
- FDA develops regulations for proper labeling. For example, FDA developed new regulations requiring cosmetic ingredient labeling, and nutrition labeling on many foods.
- FDA works with the industries it regulates to help them develop better quality control procedures.
- FDA tests drugs regularly after approval to make sure they meet standards of potency, purity and quality.
- FDA issues public warnings when hazardous products have been identified.

What FDA can and cannot do

FDA carries out the responsibilities assigned to it by the Congress. Four laws authorize the majority of FDA activities:

- The Federal Food, Drug and Cosmetic Act requires that foods be safe and wholesome, that drugs be safe and effective, and that cosmetics and medical devices be safe. All these products must be properly labeled.
- The Fair Packaging and Labeling Act requires that labeling be honest and informative, so that shoppers may easily determine the best value.
- The Radiation Control for Health and Safety Act protects consumers from unnecessary exposure to radiation from x-ray machines and consumer products such as microwave ovens and color TVs.
- The Public Health Service Act establishes FDA's authority over vaccines, serums and other biological products. It also is the basis for FDA's programs on milk sanitation, shellfish sanitation, restaurant operations and interstate travel facilities.

Many misconceptions exist about FDA's legal authority.

FDA **can** prevent some products from being sold until they are proved safe. Examples are new drugs and new food additives.

FDA **cannot** prevent an unscrupulous person from selling some products, such as worthless medical devices or harmful cosmetics, until **after** they are actually marketed. The burden is on the FDA to prove such products are worthless or harmful.

FDA generally **can** act **only** against products sold in interstate commerce. A product made and sold solely within a state usually must be regulated by that state.

FDA **can** initiate removal of a product from the market when new scientific evidence reveals unacceptable or unexpected risks. For example, FDA banned hexachlorophene as an active ingredient based on new evidence showing an unacceptable risk.

FDA **cannot** recall a product. It can ask a manufacturer to do so, however, under the threat of legal action.

FDA **can** go to court to seize illegal products and to prosecute the manufacturer, packer or shipper of adulterated or mislabeled products.

FDA **can** take action against false and misleading labeling on the products it regulates.

FDA **cannot** control the price of any product.

FDA **cannot** directly regulate the advertising of any product except prescription drugs.

FDA **cannot** regulate cigarettes.

DHEW Publication No. (FDA) 74-1021